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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,333	09/29/2005	Kenji Motokawa	082368-002100US	2713

20350 7590 02/01/2008

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EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
02/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,333	MOTOKAWA ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *Nov. 16, 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-3, 5 and 8-12 in the reply filed on December 26, 2007 is acknowledged.

Status of the Claims

Claims 1-3, 5 and 8-12 are pending and under examination. Claims 4 and 6-7 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The specification, while being enabling for an immunogenic composition, does not reasonably provide enablement for absolute prevention or elimination of viral infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The first paragraph of 35 U.S.C. 112 states: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use

the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring ingenuity beyond that to be expected of one of ordinary skill in the art (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those In the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention: The claimed invention is drawn to a vaccine for treating and/or preventing feline peritonitis. The claim contains the terms "**prevention**". The office interprets this term as denoting absolute prevention of infection of even a single cell by a virus and absolute elimination of infection of any cell by a virus.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that while vaccines are used as prophylactic treatment against specific virus infections and can reduce the incidence of or ameliorate the symptoms of viral infection, there are no treatment methods which can completely prevent viral infection in all cells in every subject.

The amount of direction or guidance present and the presence or absence of working examples: The disclosure is limited to data of vaccine trials which limit the number of deaths in a challenge study. There are no working examples drawn to absolute prevention of viral

infection *in vivo* by employing the claimed method and no working examples showing absolute prevention of infection with viruses *in vivo*. Therefore, there is insufficient evidence to ascertain that the claimed compositions actually completely prevent or totally eliminate viral infection in the subjects.

The breadth of the claims and the quantity of experimentation needed: Because the art teaches a high degree of unpredictability in the ability of vaccines to completely prevent or eliminate viral infection, because the claims encompass absolute prevention and elimination of all virus infections, and because the specification fails to provide an enabling disclosure for absolute prevention or complete elimination, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5 and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wasmoen et al. (US Patent 5,770,211, June 1998) in view of Motokawa et al. (Microbiology and Immunology, 1996, Vol. 40, No. 6, pages 425-433).

The claimed invention is drawn to a vaccine for treating and/or preventing feline infectious peritonitis, wherein said vaccine comprises a protein comprising an amino acid sequence encoded by a polynucleotide comprising SEQ ID NO: 1 or SEQ ID NO: 2. The

claimed invention is also drawn to a method for treating and/or preventing feline infectious peritonitis, comprising administering the vaccine to a cat.

Wasmoen et al. (hereinafter Wasmoen) teaches a feline infectious peritonitis virus (FIPV) vaccine comprising the N protein of FIPV (column 1, lines 65-67 and column 2, lines 1-4). Wasmoen teaches the vaccine is prepared by creating a recombinant poxvirus containing the N protein of FIPV or immunogenic fragments (column 2, lines 45-48). Wasmoen teaches administering the vaccine to a feline (column 2, lines 5-8).

Motokawa et al. (hereinafter Motokawa) teaches the SEQ ID NO: 1 and SEQ ID NO: 2 from the instant claimed invention (page 428-429, strain KU-2).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the N protein in the vaccine formulation as taught by Motokawa in SEQ ID NO: 2. The person of ordinary skill in the art would have been motivated to make that (those) modification(s) because Wasmoen teaches a FIPV vaccine comprising the N protein is effective, and reasonably would have expected success because of the teachings of Wasmoen and Motokawa.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

January 22, 2008

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